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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/601,912

06/23/2003

Richard L. Antrim

006401.00399

7581

22908 7590 07/17/2008

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EXAMINER

BLAND, LAYLA D

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

07/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/601,912	Applicant(s) ANTRIM ET AL.	
	Examiner LAYLA BLAND	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 34-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on May 6, 2008 and May 12, 2008 have been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed May 6, 2008, and amendment and response to the Final Office Action (mailed December 6, 2007), filed May 6, 2008 wherein claims 136-40 are newly submitted.

Claims 1-10 and 34-40 are pending and are examined on the merits herein.

The following rejections are record are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers et al. (US Patent 5,518,739).

Meyers et al. anticipate the claims as it teaches a maltodextrin having degree of polymerization between 4 and 27 (co1.3, line 21). Meyers et al also disclose maltodextrin derivatized with dextrin via glycosidic linkages such as α -1,6, β -1,2, β -1,3 and β -1,6 (col.3, lines 22-24). It is inherent property of a dextrin to exist in the form of dextrose, maltose (two dextrose attached with each other), maltotriose (three dextrose attached with each other), and maltotetraose (four dextrose attached with each other). Myers et al. also disclose the hydrogenated starch hydrolyzate known as sorbitol (col.3, lines 49-50). Thus, this meets the process limitations. Regarding claim 35, the limitation of how the extrusion reaction is performed does not have any patentable weight to the composition claimed in claim 1.

Claims 1-5, 7-10, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (US Patent 4,840,807).

Yoshida et al. anticipate the claims as it teaches a maltodextrin having degree of polymerization between 1 and 20 (co1.5, line 30). Yoshida et al also disclose maltodextrin derivatized with dextrin via glycosidic linkages such as α -1,6 and α -1,4 (claim 1). Dextrin is disclosed in the form of dextrose, maltose (two dextrose attached

with each other), maltotriose (three dextrose attached with each other), and maltotetraose (four dextrose attached with each other) (col 7, lines 54-62). Thus, this meets the process limitations. Regarding claim 35, the limitation of how the extrusion reaction is performed does not have any patentable weight to the composition claimed in claim 1.

Claims 1-10, 34 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Fouache et al. (US Patent 6,630,586).

Fouache et al anticipate the claims as it teaches a maltodextrin having degree of polymerization between 1 and 20 (col.5, line 30). Fouache et al. disclose maltodextrin derivatized with dextrin via glycosidic linkages such as α -1,6 and α -1,4 (claim 1). Fouache et al also disclose maltodextrin derivatized with dextrin via glycosidic linkages such as 1-2; 1-3; 1-4; and 1-6 (Co1.8, Tables I and II). Dextrin is disclosed in the form of dextrose, maltose (two dextrose attached with each other), maltotriose (three dextrose attached with each other), and maltotetraose (four dextrose attached with each other) (col 7, lines 54-62). Fouache et al. also disclose the use of sorbitol [column 4, lines 15-22].

Regarding claims 1 and 35, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

Applicant's arguments filed May 6, 2008 and May 12, 2008 have been fully considered but they are not persuasive.

Applicant argues that Yoshida et al. does not anticipate the claims because, in the product of Yoshida, there will be nothing other than alpha-1,4 and alpha-1,6 bonds in the finished product, unlike the present invention.

The rejected claims are not drawn to a product containing bonds other than alpha-1,4 and alpha-1,6 bonds, so this argument is not relevant.

Applicant argues that, as presented in the declaration of Dr. Perminus Mungara, the products of Meyers and Fouache are different from the product of the present invention.

Dr. Mungara compared only a few embodiments of the very broadly claimed instant invention. The examples are not commensurate in scope with the claims.

The instant claims are very broad. It is unclear what distinguishes the claimed products from the prior art, what properties the claimed products have, and how one would know if he or she was infringing the claimed invention.

Thus, the rejections made in the previous office action are maintained.

The following are new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-40 recite the limitation "digestibility." "Digestibility" is not clearly defined in the specification. Page 17 of the specification states that "% digest = 3 hour digestibility, adapted from J.S. White et al." There is no guidance as to how the teachings of White were adapted to arrive at the digestibility data. Furthermore, in the declaration of Dr. Perminus Mungara, submitted August 7, 2007, 4-hour digestibility (not 3-hour digestibility) is measured based on articles by Muir and O'Dea, which are not the same as that recited in the specification. Thus, because it is unclear how digestibility is determined, the meaning of the term is unclear and the claims are indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 36-40 recite the limitation "digestibility of at least 18.71%" or "at least 21.67%," or "at least 24.5%." The recitation "digestibility

of at least 18.71%” lacks of adequate written description since these recitations read literally on any composition having digestibility of 18.71-100%.

The specification as originally filed does not provide support for compositions having digestibility of 18.71-100%. It is further noted that, because the claims also require the presence of 1-2 and 1-3 bonds, 100% digestibility is unattainable. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), regarding a corresponding new claim limitation with no upper limit. See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Stahl et al. (WO 01/33973, May 17, 2001, and machine translation).

Stahl et al. teach a modified carbohydrate made of a base body and a carbohydrate residue coupled therewith [abstract]. In example A1, maltodextrin was

derivatized with glucose (dextrose monohydrate) residues [page 13, lines 8-21 of original document and page 4 of machine translation, Example 1, Variant A]. The digestible base body or carbohydrate can preferably be dextrin [page 6, lines 7-9 of original document and page 2 of machine translation, second paragraph from the bottom]. The DP of the base carbohydrate is preferably 3-100 but can be up to 100,000 [page 5, lines 12-15 of original document or page 2, paragraph 10 of the machine translation]. Products obtained by derivatization of maltodextrin with glucose in the 1-2, 1-3, 1-4, or 1-6 position are specifically claimed [claim 4].

Regarding claims 1 and 35, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698,227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fouache et al. (US Patent 6,630,586).

Fouache et al. teach as set forth above. In one example, branched maltodextrin derivatives were prepared which contain about 10% 1,2 linkages, about 10% of 1,3 linkages, about 50% of 1,4 linkages and about 30% of 1,6 linkages [column 8, Table I].

Fouache et al. do not explicitly teach the digestibility of the products.

However, it is considered very likely that the products of Fouache et al. meet the digestibility limitations of the instant claims. The declaration of Dr. Perminus Mungara, submitted August 15, 2007, states that the presence of 1,4 and 1,6 bonds suggests that the products are digestible. The percentages of 1,4 and 1,6 linkages found in Table I of Fouache et al. are higher than those shown in Table 2 of the aforementioned declaration. Thus, it seems very likely that the products in Table I of Fouache et al. are at least as digestible as the products tested in the declaration of Dr. Perminus Mungara, submitted August 15, 2007, which were found to have 4-hour digestibility of 33-42.

Claims 36-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stahl et al. (WO 01/33973, May 17, 2001, and machine translation).

Stahl et al. teach Example 1A, as set forth above. The product prepared by Example 1A has increased glucose release compared with the unmodified product [Figure 1 and page 4, second paragraph of the machine translation].

It is unclear whether the digestibility data presented by Stahl is the same assay used by Applicant to determine the claimed digestibility, and Stahl does not explicitly teach a 3-hour digestibility.

However, because the product of Example A1 has the required 1-2 and 1-3 bonds, is derived from maltodextrin and glucose as recited in several of the instant claims, has increased digestibility compared to the unmodified product, and has a glucose release of about 40 mmol/l at 90 minutes [see Figure 1], it is considered likely that the products taught by Stahl meet the claimed limitations.

Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 34-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30 and 31 of copending Application No. 11/184,989. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each application are drawn to derivatized malto-oligosaccharide mixtures prepared under the same conditions. The claims of copending Application No. 11/184,989 do not include limitations regarding 1-2 and 1-3 linking bonds or digestibility, but the products are made by the same process as the instantly claimed products, so the properties of the product would be expected to be the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10, 34, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/292,246. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to derivatized malto-oligosaccharides and the claims of copending Application No. 11/292,246 are drawn to derivatized starches. Malto-oligosaccharides are derived from starch and the instant claims do not recite an upper limit for degree of polymerization or molecular weight of the malt—oligosaccharides. The claims of copending Application

No. 11/292,246 do not include limitations regarding 1-2 and 1-3 linking bonds or digestibility, but the products are made by the same process as the instantly claimed products, so the properties of the product would be expected to be the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Tuesday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
Examiner, Art Unit 1623